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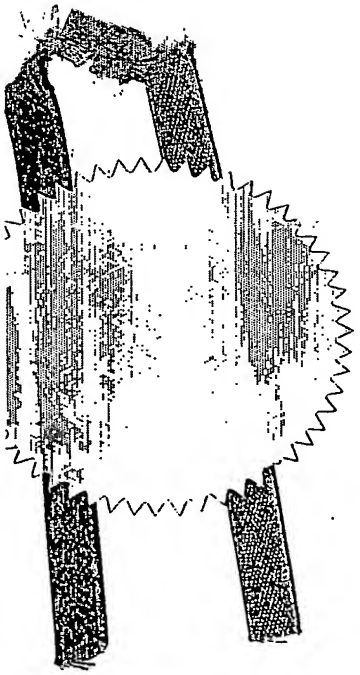

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IMPLANTABLE MEDICAL DEVICES WITH A PATCH WITH OPTIONAL POCKETS FOR SEALING ANEURYSMS AND/OR REAGENT DELIVERY AND METHODS FOR MAKING THE SAME

Field of the Invention

[0001] The present invention relates to an implantable medical device with a patch with optional pockets for sealing aneurysms and/or delivering at least one reagent into a desirable location within the endovascular system of a human body.

Background of the Invention

[0002] Vascular diseases include aneurysms causing hemorrhage, atherosclerosis causing the occlusion of blood vessels, vascular malformation and tumors. Vessel occlusion or rupture of an aneurysm within the brain causes of stroke. Tumors fed by intra-cranial arteries can grow within the brain to a point where their mass and size can cause a stroke or the symptoms of stroke, requiring surgery for removal of the tumors or other remedial intervention.

[0003] Occlusion of coronary arteries, for example, is a common cause of heart attack. Diseased and obstructed coronary arteries can restrict the flow of blood in the heart and cause tissue ischemia and necrosis. While the exact etiology of sclerotic cardiovascular disease is still in question, the treatment of narrowed coronary arteries is more defined. Surgical construction of coronary artery bypass grafts (CABG) is often the method of choice when there are several diseased segments in one or multiple arteries. Conventional open-heart surgery is, of course, very invasive and traumatic for patients undergoing such treatment. Therefore, alternative methods being less traumatic are highly desirable.

[0004] One of the alternative methods is balloon angioplasty that is a technique in which a folded balloon is inserted into a stenosis, which occludes or partially occludes an artery and is inflated to open the occluded artery. Another alternative method is atherectomy that is a technique in which occlusive atheromas are cut from the inner

surface of the arteries. Both methods suffer from reocclusion with certain percentage of patients.

[0005] A newly preferred therapy for vascular occlusions is placement of an expandable metal wire-frame including stent, within the occluded region of blood vessel to hold it open. The stent is delivered to the desired location within a vascular system by a delivery means, usually a catheter. Advantages of the stent-placement method over conventional vascular surgery include obviating the need for surgically exposing, removing, replacing, or by-passing the defective blood vessel, including heart-lung by-pass, opening the chest, and general anaesthesia.

[0006] When inserted and deployed in a vessel, duct or tract ("vessel") of the body, for example a coronary artery after dilatation of the artery by balloon angioplasty, a stent acts as a prosthesis to maintain the vessel open. The stent usually has an open-ended tubular form with interconnected struts as its sidewall to enable its expansion from a first outside diameter which is sufficiently small to allow the stent to traverse the vessel to reach a site where it is to be deployed, to a second outside diameter sufficiently large to engage the inner lining of the vessel for retention at the site. A stent is typically delivered in an unexpanded state to a desired location in a body lumen and then expanded. The stent may be expanded via the use of a mechanical device such as a balloon, or the stent may be self-expanding.

[0007] Usually a suitable stent for successful interventional placement should possess features of relatively non-allergenic reaction, good radiopacity, freedom from distortion on magnetic resonance imaging (MRI), flexibility with suitable elasticity to be plastically deformable, strong resistance to vessel recoil, sufficient thinness to minimize obstruction to flow of blood (or other fluid or material in vessels other than the cardiovascular system), and biocompatibility to avoid of vessel re-occlusion. Selection of the material of which a stent is composed, as well as design of the stent, plays an important role in influencing these features.

[0008] Furthermore, implantable medical devices have been utilized for delivery of drugs or bioreagents for different biological applications. Typically, the drugs or bioreagents are coated onto the surfaces of the implantable medical devices or mixed within polymeric materials that are coated onto the surfaces of the implantable medical

devices. However, all the current available methods suffer from one or more problems including uncontrollable release, form limitations of drugs, and bulky appearance.

[0009] Therefore, there is an imperative need to have implantable medical devices that deliver drugs or reagents efficiently to endovascular system, especially intracranial blood vessels. This invention satisfies this need by disclosing the medical devices that comprise a patch with optional pockets. Other advantages of this invention will be apparent with reference to the detailed description.

Summary of the Invention

[0010] The present invention relates to an implantable medical device with a patch with optional pockets for sealing aneurysms and/or delivering at least one reagent into a desirable location within the endovascular system of a human body. The patch with optional pockets comprises a first layer being attached to said implantable medical device, an optional intermediate layer being attached or merged to the first layer, wherein the intermediate layer comprises at least two circumferential strips being separated from each other, and an optional second layer covering the first layer and the intermediate layer, wherein the at least one reagent may be optionally deposited in the pockets formed by the first layer, the circumferential strips and the second layer. Alternatively, the intermediate layer comprises at least one opening formed within the intermediate layer.

[0011] One objective of the present invention is to use the patch (with or without pockets) as a mechanical seal (cover) of fusiform or wide-neck aneurysms

[0012] The other objectives and advantages of the invention will become apparent from the following detailed description of preferred embodiments thereof in connection with the accompanying drawings.

Brief Description of the Drawings

[0013] Preferred embodiments according to the present invention will now be described with reference to the Figures, in which like reference numerals denote like elements.

[0014] FIGS1A and 1B are two exemplary balloon expandable stents as an illustration of implantable medical devices of the present invention.

[0015] FIG 2 shows a self-expanding stent as an illustration of implantable medical devices of the present invention.

[0016] FIG 3A is diagrammatic view of a stent disposed in the location of an aneurysm, wherein a patch less than the stent seals the neck of the aneurysm and the radiopaque markers located in the middle of the stent provide the visibility of the stent during operation and post-operation inspection.

[0017] FIG 3B is diagrammatic view as FIG 3A except that a port of the stent is formed of opened cells.

[0018] FIG 4 shows a delivery system with a stent expanded onto the balloon in accordance with the present invention.

[0019] FIG 5 is diagrammatic view of a stent partially covered by a patch with pockets.

[0020] FIG 6 is a cross-sectional view of a sleeve as a patch supported by two ring-like stents.

Detailed Description of the Invention

[0021] The present invention may be understood more readily by reference to the following detailed description of certain embodiments of the invention.

[0022] Throughout this application, where publications are referenced, the disclosures of these publications are hereby incorporated by reference, in their entireties, into this application in order to more fully describe the state of art to which this invention pertains.

[0023] The present invention provides implantable medical devices that include physical structures for delivering drugs or reagents to desired sites within the endovascular system of a human body. The implantable medical devices may take up diversified shapes and configurations depending upon specific applications. Common implantable medical devices include stents, vena cava filters, grafts and aneurysm coils. While stents are used

to illustrate the present invention, it is noted that the disclosed structures and methods in the present invention are applicable to all the other implantable medical devices.

[0024] The endovascular system of a human body includes blood vessels, cerebral circulation system, tracheo-bronchial system, the biliary hepatic system, the esophageal bowel system, and the urinary tract system. While the discussion hereinafter of the present invention utilizes exemplary stents implantable in blood vessels, the present invention is applicable to the remaining endovascular system.

[0025] Stents are expandable prostheses employed to maintain vascular and endoluminal ducts or tracts of the human body open and unoccluded, such as a portion of the lumen of a coronary artery after dilatation of the artery by balloon angioplasty. A typical stent is a generally tubular structure having an exterior surface defined by a plurality of interconnected struts having interstitial spaces there between. The generally tubular structure is expandable from a first position, wherein the stent is sized for intravascular insertion, to a second position, wherein at least a portion of the exterior surface of the stent contacts the vessel wall. The expanding of the stent is accommodated by flexing and bending of the interconnected struts throughout the generally tubular structure. It is contemplated that many different stent designs can be produced. A myriad of strut patterns are known for achieving various design goals such as enhancing strength, maximizing the expansion ratio or coverage area, enhancing longitudinal flexibility or longitudinal stability upon expansion, etc. One pattern may be selected over another in an effort to optimize those parameters that are of particular importance for a particular application.

[0026] Now referring to FIGS 1A and 1B, there are provided two exemplary balloon expandable stent designs. FIG 1A shows a tubular balloon expandable stent **100** with end markers **103** for further visibility. The stent **100** is composed of stent struts of a ring **101**, ring connectors **102**, and end markers **103**. As shown in FIG. 1A, the stents **100** are made of multiple circumstantial rings **101**, where the ring connectors **102** connect two or three adjacent rings **101** to hold the rings in place. For the end markers **103**, FIG. 1A shows a "disc" shaped marker. Actually, the shape is not critical so long that the marker can be used to add further visibility to the stents. FIG. 1B shows a tubular balloon expandable stent **104** which is similar to the stent **100** as shown in FIG. 1A except that the

stent **104** comprises of center markers **105, 106**. The center markers **105, 106** help to locate an aneurysm opening during an implantation operation. The center markers can be of the same material and shape as the end markers.

[0027] Now referring to FIG 2, there is provided a self-expanding stent **107** that is made of wires/ribbons. While a self-expanding stent may have many designs, FIG2 shows the stent **107** having a typical braided pattern **108** with welded ends **109**. The stent **107** is so designed that is relatively flexible along its longitudinal axis to facilitate delivery through tortuous body lumens, but that is stiff and stable enough radially in an expanded condition to maintain the patency of a body lumen, such as an artery when implanted therein. Referring briefly to FIG 4, it is shown an expanded tubular stent **112**. When the tubular stent **112** is fully expanded to its deployed diameter, the latticework of struts takes on a shape in which adjacent crests undergo wide separation, and portions of the struts take on a transverse, almost fully lateral orientation relative to the longitudinal axis of the stent. Such lateral orientation of a plurality of the struts enables each fully opened cell to contribute to the firm mechanical support offered by the stent in its fully deployed condition, to assure a rigid structure which is highly resistant to recoil of the vessel wall following stent deployment. It bears emphasis, however, that the configuration of this stent structure, while highly desirable, is illustrative only and not essential to the principles of the present invention.

[0028] While a stent may be deployed by radial expansion under outwardly directed radial pressure exerted, for example, by active inflation of a balloon of a balloon catheter on which the stent is mounted, the present inventors also contemplate that the stent may be self-expandable. In some instances, passive spring characteristics of a preformed elastic (i.e., self-opening) stent serve the purpose. The stent is thus expanded to engage the inner lining or inwardly facing surface of the vessel wall with sufficient resilience to allow some contraction but also with sufficient ~~stiffness to~~ largely resist the natural recoil of the vessel wall.

[0029] In certain embodiments of the present invention, the implantable medical devices are intracranial stents and delivery systems for stenotic lesions and aneurysms. Due to the characteristics of intracranial blood vessels, the intracranial stents may be designed to be very flexible, low profile (0.033" – 0.034" or even less as crimped onto

delivery catheter) and thin wall (0.0027"- 0.0028"). The intracranial stents do not necessarily have the highest possible radial strength because there is no need of high strength for intracranial applications. The radiopacity of the intracranial stents may be provided by either including radiopaque markers made from gold or platinum or making the stents from platinum/iridium/tangsten alloys. Stents for aneurysms may have special type platimum "star markers" in the middle of their bodies to assist in precise indication and alignment of the stents over aneurysm neck and allow further operations with aneurysms. As shown in FIG 3A, the stent **202** is disposed in the location of an aneurysm **201**, wherein a patch **203** less than the stent seals the neck of the aneurysm and the radiopaque markers **204** located in the middle of the stent provide the visibility of the stent during operation and post-operation inspection. Referring to FIG 3B, a portion of the stent is formed of opened cells **205**. This design is very useful in avoidance of blocking perforations **204**. The perforations refer to small capillary vessels that have important and distinctive blood supply functions. It is very possible that normally tubular stents can block perforations and inhibit important functions. The patch **203** will be discussed in detail hereinafter.

[0030] Stents may be manufactured in any manner known to one skilled in the arts. All suitable materials for making the stents are also known to one skilled in the arts. There is no further discussion of the material selection for the stents and the methods used for making the stents in order not to obscure the present invention..

[0031] Referring still to FIG 4, the delivery system includes a guide wire lumen **110**, a balloon inflating lumen **111**, a connector **116**, a balloon catheter shaft **113**, and platinum marker bands **115** on the catheter shaft **113**. The guide wire lumen **110** is used for introducing a guide wire in a balloon catheter, and the balloon inflating lumen **111** for inflating the balloon after the stent to be placed reaches its targeted location. The connector **116** is used for separating the guide wire lumen **110** and the balloon inflating lumen **111**. The balloon catheter shaft **113** carries the guide wire lumen **110** and the balloon inflating lumen **111** separately, with a typical length of about 135-170 cm. The ring markers **115** on the catheter shaft **113** is used for showing the start of balloon tapers and the edges of the stent. In FIG. 3, an expanded stent **112** is shown being mounted onto an expanded balloon. The delivery catheter can be essentially a conventional balloon

dilatation catheter used for angioplasty procedures. The balloon may be formed of suitable materials such as irradiated polyethylene, polyethylene terephthalate, polyvinylchloride, nylon, and copolymer nylons such as Pebax™. Other polymers may also be used. In order for the stent to remain in place on the balloon during delivery to the desired site within an artery, the stent is crimpped onto the balloon.

[0032] In a preferred embodiment, the delivery of the stent is accomplished in the following manner. The stent is first mounted onto the inflatable balloon on the distal extremity of the delivery catheter. Stent is mechanically crimped onto the exterior of the folded balloon. The catheter/stent assembly is introduced within vasculature through a guiding catheter. A guide wire is disposed across the diseased arterial section and then the catheter/stent assembly is advanced over a guide wire within the artery until the stent is directly under the diseased lining. The balloon of the catheter is expanded, expanding the stent against the artery. The expanded stent serves to hold open the artery after the catheter is withdrawn. Due to the formation of the stent from an elongated tube, the undulating component of the cylindrical elements of the stent is relatively flat in transverse cross-section, so that when the stent is expanded, the cylindrical elements are pressed into the wall of the artery and as a result do not interfere with the blood flow through the artery. The cylindrical elements of the stent which are pressed into the wall of the artery will eventually be covered with endothelial cell layer which further minimizes blood flow interference. Furthermore, the closely spaced cylindrical elements at regular intervals provide uniform support for the wall of the artery, and consequently are well adopted to tack up and hold in place small flaps or dissections in the wall of the artery.

[0033] For resilient or self-expanding prostheses, they can be deployed without dilation balloons. Self-expanding stents can be pre-selected according to the diameter of the blood vessel or other intended fixation site. While their deployment requires skill in stent positioning, such deployment does not ~~require~~ the additional skill of carefully dilating the balloon to plastically expand the prosthesis to the appropriate diameter. Further, the self-expanding stent remains at least slightly elastically compressed after fixation, and thus has a restoring force which facilitates acute fixation. By contrast, a plastically expanded stent must rely on the restoring force of deformed tissue, or on hooks, barbs, or other independent fixation elements.

[0034] It is well known that the presence of a stent in a vessel tends to promote thrombus formation as blood flows through the vessel, which results in an acute blockage. In addition, as the outward facing surface of the stent in contact or engagement with the inner lining of the vessel, tissue irritation can exacerbate restenosis attributable to hyperplasia. Moreover, it is desirable to deliver drugs or reagents into the aneurysms to enhance the blockage of blood flow into the aneurysms. Finally, implantable medical devices have been used as vehicles to deliver drugs or reagents to specific locations within the vascular system of a human body.

[0035] The present invention provides patches disposed onto the outer surfaces of implantable medical devices, wherein the patches may comprise pockets serving as receptacles for drugs or reagents so that the drugs or reagents may be delivered into vascular systems. The patches may cover a part of a stent as shown in FIG 3A and FIG 3B, wherein the sizes of the patches may be varied in accordance with any specific application. In one extreme, the patch may cover the whole outer surface of a stent. Thus, the "patch" may be in any shape and size formed in accordance with the present invention.

[0036] In certain embodiments, the patch with optional pockets comprises a first layer being attached to the outer surface of an implantable medical device such as stents, an optional intermediate layer being attached to the first layer wherein the intermediate layer comprises at least two circumferential strips being separated from each other and an optional second layer covering the first layer and the intermediate layer. The spaces surrounded by the first layer, the circumferential strips and the second layer form the optional pockets that serve as receptacles for drugs or reagents. In other embodiments, the intermediate layer includes at least one opening so that the optional pockets can be formed within the openings. The shapes and sizes of the openings may vary in accordance with specific applications. As shown in FIG 5, a stent **202** may be partially covered by a patch **203** that comprises a first layer **206** and a second layer **207**. FIG 5 also shows the drug releasing pores **208**.

[0037] Many polymeric materials are suitable for making the layers of the patches. The present invention takes the advantage of expanded polytetrafluoroethylene ("ePTFE") that is a porous and at least uniaxially expanded material. The ePTFE-material can exhibit different shapes, for example a foil, sheet or tube. ePFFE exhibits superior

biocompatibility and is suitable for vascular applications as a result of its low thrombogenicity. ePTFE can form specified shape and size pores by controlling its molecular weight and concentration during the making of ePTFE films and tubing. Thus, pockets with different ePTFE layers are conceived. The pockets would be major carriers for an implantable medical device of at least one reagent delivered to a lesion site. Typically, one first layer is disposed onto the outer surface of a stent. The first layer has a thickness of 0.002" – 0.005" with pore sizes of 20 –30 microns and similar to nominal initial diameter.

[0038] In certain embodiments, the first layer can serve as an independent patch (without pockets) to just mechanically cover and seal aneurysms.

[0039] In certain embodiments, the first and/or second layers can be comprised of biodegradable material as a drug or reagent carrier for sustained release.

[0040] It is desirable that the intermediate layer be formed of a material which can fuse to the first and second layers or attached to the first layer in a different manner. In certain embodiments, the intermediate layer may be merged with the first layer to form a single layer with recessions within the outer surface of the merged layer. In other embodiments, the intermediate layer is preferably formed of FEP (fluorinated ethylene polypropylene) because this material is very compatible with the ePTFE material utilized for the first and second layers and it bonds (fuses) to ePTFE when subjected to heat. Alternatively the intermediate layer can be formed of PTFE which can be bonded to the first and second layers by suitable means such as an adhesive or ultrasonic welding, or suturing.

[0041] The second and intermediate layers can be made of biodegradable material that contains drugs or reagents for immediate or sustained controlled release. After biodegradable material is gone through the degradation process, ePTFE is still in tact providing vessel support.

[0042] The second layer may be composed of a polymeric material. In preferred embodiments, the second layer is made of ePTFE, wherein the ePTFE layer has a preferable thickness of about 0.001" with pore sizes of about 70 – 100 microns.

[0043] In the present invention, the polymeric layers may also be formed from a material selected from the group consisting of fluoropolymers, polyimides, silicones,

polyurethanes, polyurethanes ethers, polyurethane esters, polyurethaneureas and mixtures and copolymers thereof. Biodegradable polymeric materials can also be used.

[0044] The present invention contemplates adhering, laminating, suturing or otherwise bonding fusible polymeric layers. The fusion of the polymeric layers may be achieved by various techniques such as heat-sealing, solvent bonding, adhesive bonding or use of coatings.

[0045] Various adhesives (as opposed to directly adhering PTFE to PTFE) can also be used to create the bonding between two layers. This adhesive may be one that is "activatable" meaning that the material is not inherently sticky as it is applied. However, it can be activated by applying heat, light or some other energy so that it hardens or otherwise changes to form a permanent bond. A number of different activatable adhesive materials can be used in the present invention. One such material might be a layer or coating of a thermoplastic such as polyethylene. This material can be activated by heat that melts it so that it flows into the pores of the ePTFE. After cooling the plastic hardens so that the ePTFE layers are bonded. Alternatively, an inherently sticky adhesive can also be employed.

[0046] Types of drugs or reagents that may prove beneficial include substances that reduce the thrombogenic, inflammatory or smooth muscle cell proliferative response of the vessel to the implantable medical devices. For example, cell inhibitors can be delivered in order to inhibit smooth muscle cells proliferation. In intracranial or some other applications fibrin sealants can be used and delivered to seal aneurysm neck and provide fibroblasts and endothelial cells growth. Specific examples of drugs or reagents may include heparin, phosporylcholine, albumin, dexamethasone, paclitaxel and vascular endothelial growth factor (VEGF).

[0047] The drug or reagents can be incorporated into the implantable medical devices in various ways. For example the drug or reagent can be injected in the form of a gel, liquid or powder into receptacles of the pockets. Alternatively the drug or reagent can be supplied in a powder which has been formed into a solid tablet positioned in the receptacles. Such tablets would gradually dissolve after implantation because of the porous nature of the first and second layers formed of ePTFE.

[0048] Now, a preferred method of making the patches with pockets as receptacle for drugs or reagents is described. Initially, the implantable medical device such as a stent is disposed onto a mandrel that gives support for the device in the following successive steps. The supporting means may be any suitable one known to one skilled in the art. Then, the first layer such as a ePTFE layer is disposed onto the outer surface of the stent. The first layer may be adhered or bonded onto the stent at this time or a later time. Next, the intermediate layer is disposed onto the first layer if the intermediate layer is a separate layer. If the intermediate layer has merged with the first layer, then this step can be omitted. Prior to disposition of the second layer, at least one reagent in a suitable form is disposed into the pockets served as receptacles formed by the space between two circumferential strips or the opening on the intermediate layer. Finally, the second layer is disposed onto the intermediate layer and the first layer, thereby the at least one reagent is sealed within the receptacles.

[0049] The techniques of making layers together are well known to one skilled in the arts. Therefore, there is no detailed discussion about the ways to bond or adhere the layers together.

[0050] The present invention further provides that a third polymeric layer is disposed onto the inner surface of the stent, wherein the third layer is secured to the first layer so that the stent is sandwiched by the first layer and the third layer. The techniques for adding this third layer are well known to one skilled in the art.

[0051] The present invention also provides different pockets formed in a stent serving as receptacles for delivering drugs or reagents. As discussed hereinbefore, a stent is a generally tubular structure having a plurality of interconnected struts that form interstitial cells therebetween. The pockets may be formed within the interstitial cells by pressing a radiopaque marker onto their inner surfaces and covering by a polymeric layer the interstitial cells with the radiopaque marker. The radiopaque marker is made of gold or platinum. The polymeric layer may be made of biodegradable material as well as the polymeric materials as disclosed hereinabove. The drugs or reagents have also been discussed hereinabove.

[0052] The pockets formed by the spaces provided by the radiopaque markers, the interstitial cells and the polymeric layer are ideal for delivering drugs or reagents into

small vessels because of its flexibility and low profle. For example, access to small occluded arteries of the brain to allow adequate blood flow (Ischemic) or repair ruptured aneurysm is highly desirable for treating millions of people who suffer from stroke each year. One of the technical prerequisites for successful treatment in these respects is the availability of a stent, and related delivery system, which is sufficiently small and thin that it can navigate and be and deployed in these tiny vessels without occluding or damaging the lumen thereof. It is also essential that the stent be highly visible during and after implantation to enable proper deployment and aftercare by the physician. The latter attribute is especially important for treatment of intracerebral arteries, because of the obstacle to x-rays presented by the skull which makes precise visualization of a small thin stent extremely difficult. The stent should, therefore, be sufficiently radiopaque without need for its struts to be made so thick that the stent itself creates an unacceptable obstruction of the lumen of the vessel or too stiff to navigate through tortuous intracranial anatomy. Another prerequisite of a successful treatment of these extremely small diameter vessels is that the stent delivery system should be highly flexible to allow it to be advanced along the anatomy of the cerebral circulation. In addition, the total stent delivery system must be of extremely small profile, to treat diseased intra-cranial arteries generally ranging from 1.5mm to 5mm.

[0053] Referring to FIG 6, in certain embodimetns a patch can be presented as a sleeve **301** supported by two ring-like short stents **302** at both ends of a device so that the patch covers the whole area of the device. There is no scaffold support in the middle of the device. Radiopaque markers **303** may be located at both ends of the device. Depending on applications the rings can be balloon expandable and made from Stainless Steel or self-expandable made from NiTi (memory shaped nickel- titanium alloy).

[0054] While the present invention has been described with reference to particular embodiments, it will be understood that the embodiments are illustrative and that the invention scope is not so limited. Alternative embodiments of the present invention will become apparent to those having ordinary skill in the art to which the present invention pertains. Such alternate embodiments are considered to be encompassed within the spirit and scope of the present invention. Accordingly, the scope of the present invention is described by the appended claims and is supported by the foregoing description.

Claims

What is claimed is:

1. An implantable medical device with a patch with optional pockets for sealing aneurysms and/or delivering at least one reagent into a desirable location within the endovascular system of a human body, wherein the patch with optional pockets comprises:

a first layer being attached to said implantable medical device;

an optional intermediate layer being attached or merged to the first layer, wherein the intermediate layer comprises at least two circumferential strips being separated from each other; and

an optional second layer covering the first layer and the intermediate layer;

wherein the at least one reagent is deposited in the optional pockets formed by the first layer, the circumferential strips and the second layer.

2. The implantable medical device of claim 1, wherein the first layer is made of at least one polymeric material.

3. The implantable medical device of claim 2, wherein the first layer is made of ePTFE.

4. The implantable medical device of claim 3, wherein the ePTFE first layer has a preferable thickness of about 0.002 – 0.005" with pore sizes of about 20 – 30 microns.

5. The implantable medical device of claim 1, wherein the intermediate layer is made of at least one polymeric material.

6. The implantable medical device of claim 5, wherein the intermediate layer is made of ePTFE, FEP or biodegradable material.

7. The implantable medical device of claim 6, wherein the biodegradable material may form multiple sub-layers mixed with drugs or reagents.

8. The implantable medical device of claim 1, wherein the second layer is made of at least one polymeric material.

9. The implantable medical device of claim 8, wherein the second layer is made of ePTFE or biodegradable material.

10. The implantable medical device of claim 9, wherein the biodegradable material may form multiple sub-layers mixed with drugs or reagents.

11. The implantable medical device of claim 9, wherein the ePTFE layer has a preferable thickness of about 0.001" with pore sizes of about 70 – 100 microns.

12. The implantable medical device of claim 1, wherein the first layer, the intermediate layer and the second layer are made of at least one polymeric material.

13. The implantable medical device of claim 12, wherein the first layer is made of ePTFE with a preferable thickness of 0.002 – 0.005" with pore sizes of about 20 – 30 microns, the intermediate layer is made of ePTFE or FEP, and the second layer is made of ePTFE with a preferable thickness of 0.001" with pore sizes of about 70 – 100 microns. Biodegradable material that have several layers mixed with drugs or reagents itself can be used.

14. The implantable medical device of claim 1, wherein the implantable medical device is a stent.

15. The implantable medical device of claim 14, wherein the patch with optional pockets is a tubular structure with the first layer having a diameter similar to the nominal

initial diameter of the stent; and wherein the patch with optional pockets is disposed onto the outer surface of the stent.

16. The implantable medical device of claim 14, wherein the patch with optional pockets is a segment of a tubular structure disposed onto a portion of the outer surface of the stent.

17. The implantable medical device of claim 14, further comprising a third polymeric layer disposed onto the inner surface of the stent; wherein the third layer is secured to the first layer so that the stent is sandwiched by the first layer and the third layer.

18. The implantable medical device of claim 1, wherein the at least one reagent is in any form selected from the group consisting of solid tablet, liquid and powder.

19. An implantable medical device with a patch with optional pockets for sealing aneurysms and/or delivering at least one reagent into a desirable location within the endovascular system of a human body, wherein the patch with optional pockets comprises:

a first layer being attached to said implantable medical device;

an optional intermediate layer being attached to the first layer, wherein the intermediate layer comprises at least one opening formed within the intermediate layer; and

an optional second layer covering the first layer and the intermediate layer;

wherein the at least one reagent is deposited in the optional pockets formed by the first layer, the opening and the second layer.

20. The implantable medical device of claim 19, wherein the first layer is made of at least one polymeric material.

21. The implantable medical device of claim 20, wherein the first layer is made of ePTFE.

22. The implantable medical device of claim 21, wherein the ePTFE first layer has a preferable thickness of about 0.002 – 0.005" with pore sizes of about 20 – 30 microns.

23. The implantable medical device of claim 19, wherein the intermediate layer is made of at least one polymeric material.

24. The implantable medical device of claim 23, wherein the intermediate layer is made of ePTFE, FEP or biodegradable material.

25. The implantable medical device of claim 24, wherein the biodegradable material may form multiple sub-layers mixed with drugs or reagents.

26. The implantable medical device of claim 19, wherein the second layer is made of at least one polymeric material.

27. The implantable medical device of claim 26, wherein the second layer is made of ePTFE or biodegradable material.

28. The implantable medical device of claim 27, wherein the biodegradable material may form multiple sub-layers mixed with drugs or reagents.

29. The implantable medical device of claim 27, wherein the ePTFE layer has a preferable thickness of about 0.001" with pore sizes of about 70 – 100 microns.

30. The implantable medical device of claim 19, wherein the first layer, the intermediate layer and the second layer are made of at least one polymeric material.

31. The implantable medical device of claim 30, wherein the first layer is made of ePTFE with a preferable thickness of 0.002 – 0.005" with pore sizes of about 20 – 30 microns, the intermediate layer is made of ePTFE or FEP, and the second layer is made of ePTFE with a preferable thickness of 0.001" with pore sizes of about 70 – 100 microns.

Biodegradable material that have several layers mixed with drugs or reagents itself can be used.

32. The implantable medical device of claim 19, wherein the implantable medical device is a stent.

33. The implantable medical device of claim 32, wherein the patch with optional pockets is a tubular structure with the first layer having a diameter similar to the nominal initial diameter of the stent; and wherein the patch with optional pockets is disposed onto the outer surface of the stent.

34. The implantable medical device of claim 32, wherein the patch with optional pockets is a segment of a tubular structure disposed onto a portion of the outer surface of the stent.

35. The implantable medical device of claim 32, further comprising a third polymeric layer disposed onto the inner surface of the stent; wherein the third layer is secured to the first layer so that the stent is sandwiched by the first layer and the third layer.

36. The implantable medical device of claim 19, wherein the at least one reagent is in any form selected from the group consisting of solid tablet, liquid and powder.

37. A method of making an implantable medical device with a patch with optional pockets for sealing aneurysms and/or delivering at least one reagent into a desirable location within the endovascular system of a human body, wherein the patch with optional pockets comprises a first layer being attached to said implantable medical device, an optional intermediate layer being attached or merged to the first layer, wherein the intermediate layer comprises at least two circumferential strips being separated from each other or at least one opening formed within the intermediate layer, and an optional second layer covering the first layer and the intermediate layer, wherein the at least one reagent is

deposited in the optional pockets formed by the first layer, the circumferential strips and the second layer, said method comprising the following steps of:

disposing the medical device onto a mandrel;

disposing the first layer onto the outer surface of the medical device;

optionally disposing the intermediate layer onto the first layer;

optionally disposing the at least one reagent into the pockets formed by the spaces between two circumferential strips or the opening on the intermediate layer; and

optionally disposing the second layer onto the intermediate layer and the first layer; thereby the at least one reagent is sealed within the pockets.

38. The method of claim 37, wherein the disposing techniques are selected from the group consisting of suture, lamination, and adhesion.

39. The method of claim 37, wherein the first layer is made of at least one polymeric material.

40. The method of claim 37, wherein the first layer is made of ePTFE.

41. The method of claim 40, wherein the ePTFE first layer has a preferable thickness of about 0.002 – 0.005" with pore sizes of about 20 – 30 microns.

42. The method of claim 37, wherein the intermediate layer is made of at least one polymeric material.

43. The method of claim 42, wherein the intermediate layer is made of ePTFE, FEP or biodegradable material.

44. The method of claim 43, wherein the biodegradable material may form multiple sub-layers mixed with drugs or reagents.

45. The method of claim 37, wherein the second layer is made of at least one polymeric material.

46. The method of claim 45, wherein the second layer is made of ePTFE or biodegradable material.

47. The method of claim 46, wherein the ePTFE layer has a preferable thickness of about 0.001" with pore sizes of about 70 – 100 microns.

48. The method of claim 45, wherein the biodegradable material may form multiple sub-layers mixed with drugs or reagents.

49. The method of claim 37, wherein the first layer, the intermediate layer and the second layer are made of at least one polymeric material.

50. The method of claim 49, wherein the first layer is made of ePTFE with a preferable thickness of 0.002 – 0.005" with pore sizes of about 20 – 30 microns, the intermediate layer is made of ePTFE or FEP, and the second layer is made of ePTFE with a preferable thickness of 0.001" with pore sizes of about 70 – 100 microns.

51. The method of claim 37, wherein the implantable medical device is a stent.

52. The method of claim 51, wherein the patch is a tubular structure with the first layer having a diameter similar to the nominal initial diameter of the stent.

53. The method of claim 51, wherein the patch are a segment of a tubular structure disposed onto a portion of the outer surface of the stent.

54. The method of claim 51, wherein the implantable medical device further comprises a third polymeric layer disposed onto the inner surface of the stent; wherein the third layer

is secured to the first layer so that the stent is sandwiched by the first layer and the third layer.

55. The method of claim 37, wherein the at least one reagent is in any form selected from the group consisting of solid tablet, liquid and powder.

56. A stent with at least one receptacle for delivering at least one reagent to the endovascular system of a human body, said stent comprising:

a generally tubular structure made of at least one metal material; wherein the tubular structure has a plurality of interconnected struts that form interstitial cells therebetween;

a radiopaque marker being pressed onto the inner surface of at least one interstitial cell of said stent; and

a polymeric layer covering the at least one interstitial cell with the radiopaque marker;

wherein the at least one receptacle is formed within the at least one interstitial cell by the radiopaque marker and the polymeric layer; and wherein the at least one reagent is disposed within the at least one receptacle.

57. The stent of claim 56, wherein the radiopaque marker is made of gold or platinum.

58. The stent of claim 56, wherein the polymeric layer is made of biodegradable material.

59. The stent of claim 56, wherein the at least one reagent is in any form selected from the group consisting of solid tablet, liquid and powder.

60. A method for manufacturing a stent with at least one receptacle for delivering at least one reagent to the endovascular system of a human body, wherein the stent comprises a generally tubular structure made of at least one metal material and having a plurality of interconnected struts that form interstitial cells therebetween, a radiopaque marker being

pressed onto the inner surface of at least one interstitial cell of said stent, and a polymeric layer covering the at least one interstitial cell with the radiopaque marker, wherein the at least one receptacle is formed within the at least interstitial cell by the radiopaque marker and the polymeric layer, and wherein the at least one reagent is disposed within the at least one recetacle, said method comprising the following steps of:

pressing the radiopaque marker into the receptacle by using a fine mandrel with round tip;

disposing the at least one reagent within the at least one receptacle; and

disposing the polymeric layer over the at least one receptacle, thereby the at least one reagent is sealed within the at least one receptacle.

61. The stent manufacturing method of claim 60, wherein the disposing techniques are selected from the group consisting of suture, lamination, and adhesion, heat or dip coating.

62. The stent manufacturing method of claim 60, wherein the radiopaque is made of gold or platinum.

63. The stent manufacturing method of claim 60, wherein the polymeric layer is made of biodegradable material.

64. The stent manufacturing method of claim 60, wherein the at least one reagent is in any form selected from the group consisting of solid tablet, liquid, film and powder.

65. Stent or stent like sleeve supported by rings at its extreme ends.

IMPLANTABLE MEDICAL DEVICES WITH A PATCH WITH OPTIONAL POCKETS FOR SEALING ANEURYSMS AND/OR REAGENT DELIVERY AND METHODS FOR MAKING THE SAME

ABSTRACT

The present invention relates to an implantable medical device with a patch with optional pockets for sealing aneurysms and/or delivering at least one reagent into a desirable location within the endovascular system of a human body. The patch with optional pockets comprises a first layer being attached to said implantable medical device, an optional intermediate layer being attached or merged to the first layer, wherein the intermediate layer comprises at least two circumferential strips being separated from each other, and an optional second layer covering the first layer and the intermediate layer, wherein the at least one reagent may be optionally deposited in the pockets formed by the first layer, the circumferential strips and the second layer. Alternatively, the intermediate layer comprises at least one opening formed within the intermediate layer.

FIG 3A

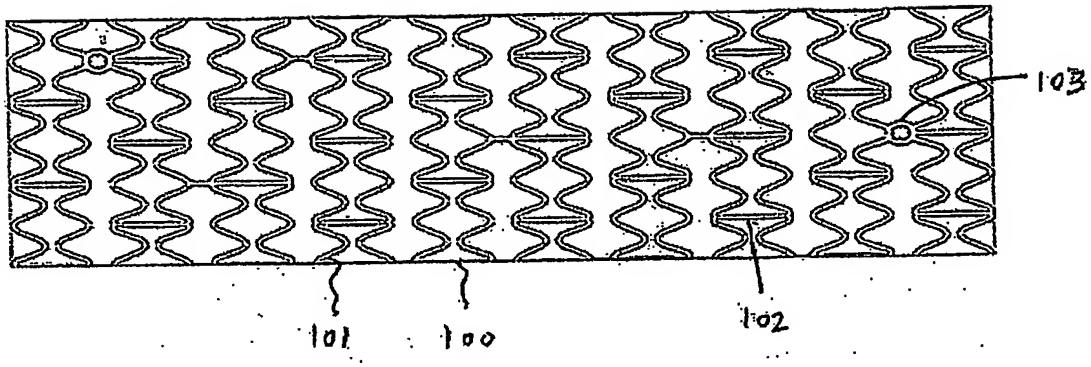

FIG. 1A

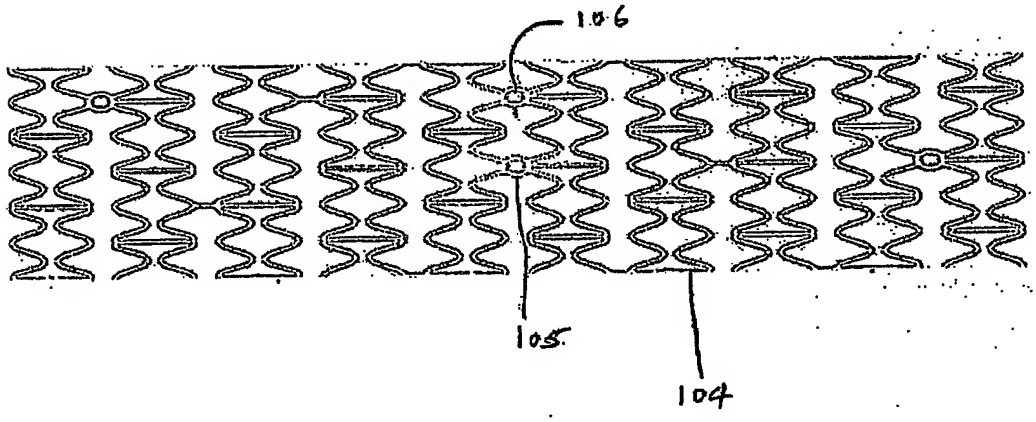

FIG. 1B

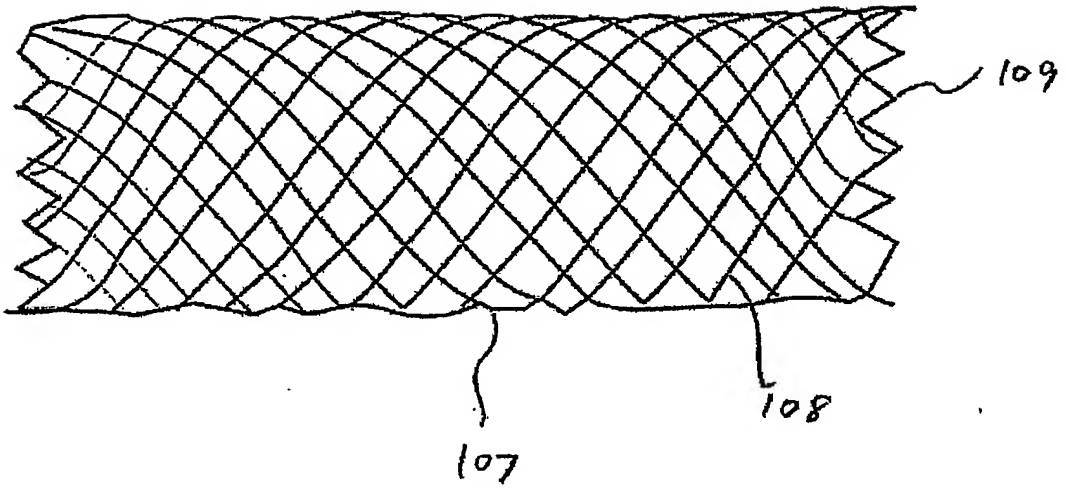

FIG. 2

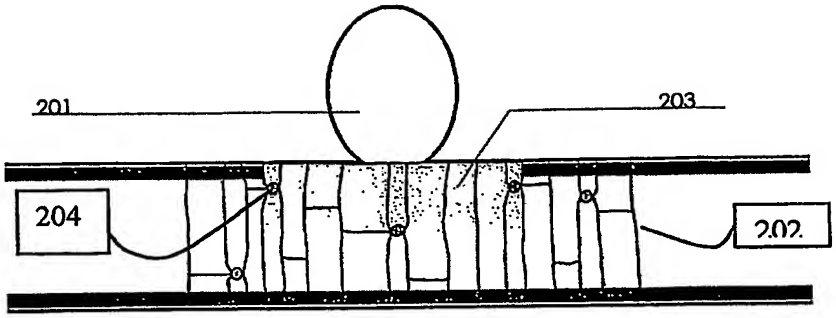

FIG 3A

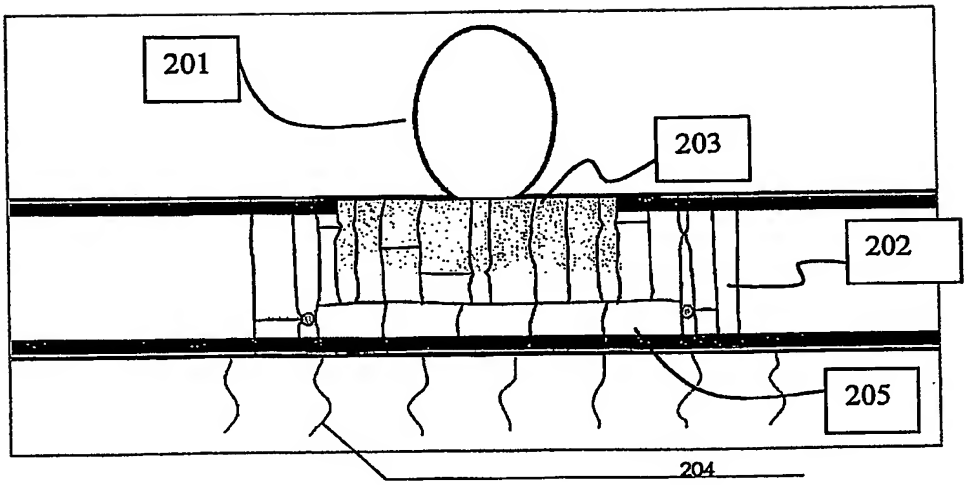

FIG 3B

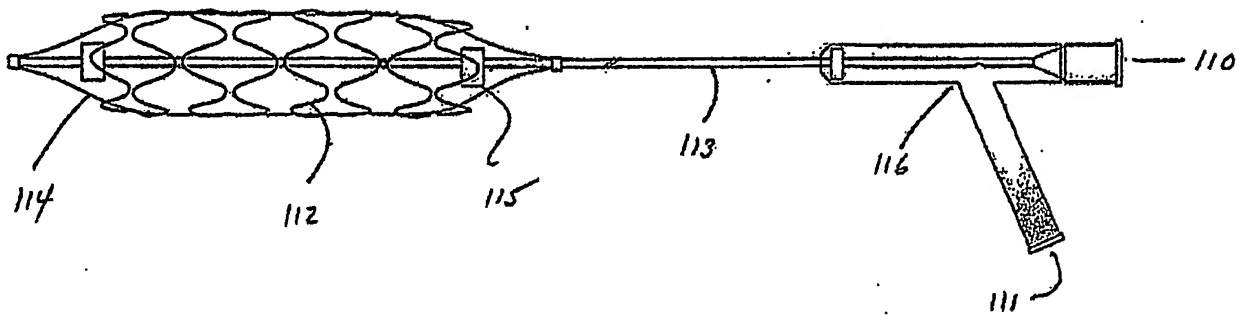

FIG 4

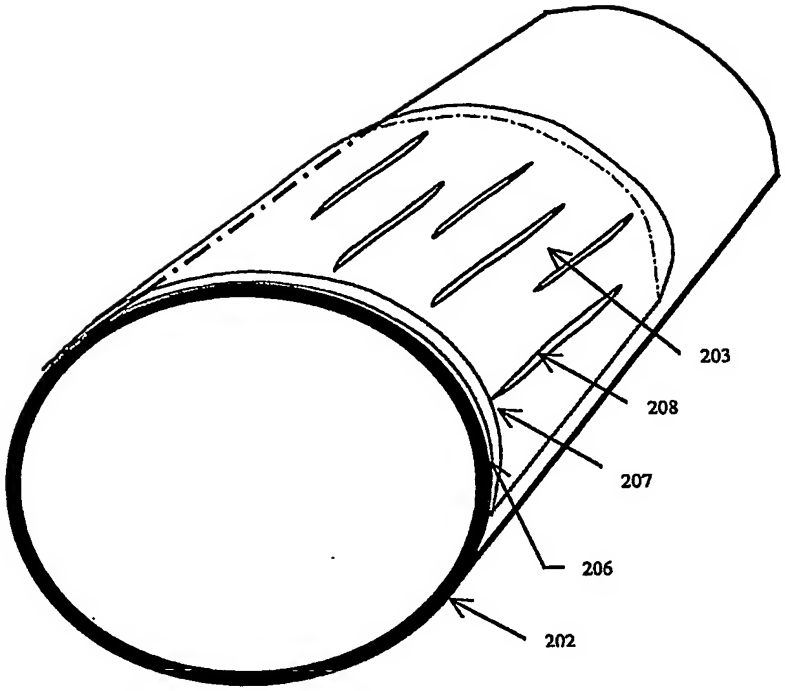

FIG 5

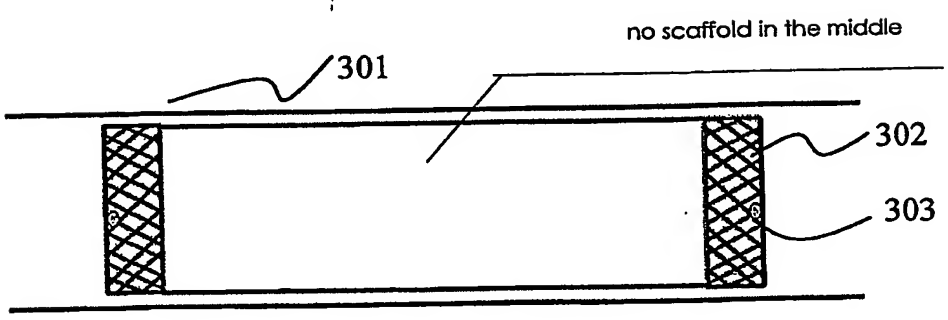

FIG 6